K081073

510(k) Summary

DEC 0 5 2008

Pausch, LLC
510(k) Pre-market Notification; HDR Vision

Date:	March 28th, 2008
Submitter's Name:	Pausch, LLC
Submitter's Address:	808 Shrewsbury Avenue Tinton Falls, NJ 07724-3002
Submitter's Contact:	Justin Tice, President
Submitter's Telephone Number:	(732) 747-6110
Submitter's Fax Number:	(732) 747-6882
Establishment Registration Number:	2243057

Device Name and Classification

Trade Name:	HDR Vision	CFR Section:	21 CFR § 892.1650
Classification Panel:	Radiology	Device Class:	Class II
Classification Name:	Image intensified fluoroscopic X-ray System	Device Code:	MQB, OWB, JAA
Common Name:	Fluoroscopic digital flat panel detector system		

Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Device Claiming Substantial Equivalence to:	Siemens Medical Systems AXIOM Luminos dRF 510(k) Control Number: K062623
Reason For Submission	New device

Description of this Device:
The HDR Vision is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies.
The HDR Vision is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography and digital subtraction angiography (DSA).

Summary of Intended Uses:
This system is intended for use as a general radiography device for the head, chest, abdomen, spine, neck and limbs. This system is used for image acquisition, image display, and the transmission/output of images to external devices. Excluded indications include mammography, computed tomography.
HDR Vision is a universal fluoroscopic x-ray diagnostic system (RIF system), with an overtable X-ray

tube assembly. Using a digital flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations.

The HDR Vision with Flat Detector is substantially equivalent to the commercially available AXIOM Luminos dRF with Flat Detector Siemens system.
The AXIOM Luminos dRF with Flat Detector, and generally marketed as the AXIOM Luminos dRF, was described in premarket notification K062623 which received FDA Clearance on August 22, 2007.

The Flat Panel Detector Pixium RF 4343 manufactured by Trixell and equipped with the HDR Vision is substantially equivalent to the Pixium 5100 manufactured by Trixell and equipped with the AXIOM Luminos dRF that was described in premarket notification K062623 which received FDA Clearance on August 22, 2007.

HDR Vision can be configured as a single tube system, with only an overtable tube or it can be combined with an additional 3D overhead tube crane, that can be moved longitudinally and laterally as well as vertically and a bucky wall stand.

Technological Characteristics:
This device employs similar materials and processes as found in the predicate device. The device produces ionizing radiation that is employed to generate radiographic and fluoroscopic images of the anatomy. HDR Vision is not a stand-alone device, but functions as the platform for specific X-ray components, X-ray tube and housing, flat detector, digital imaging system, Bucky wall stand, collimator, generator etc. Many of the components used in HDR Vision are either commercially available with current Pausch systems or include minor modifications to existing components.

Safety and Effectiveness Concerns:
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the HDR Vision is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with, and responsible for, the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Pausch adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

Conclusion:
The HDR Vision complies with the same or equivalent standards and has the same intended use as the predicate device and does not raise new questions of safety or effectiveness and is substantially equivalent to the Siemens AXIOM Luminos dRF; K062623 (August 22, 2007).

End of 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Justin Tice
President
PAUSCH LLC
808 Shrewsbury Avenue
TINTON FALLS NJ 07724

JUL 30 2012

Re: K081073
Trade/Device Name: HDR Vision
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, and MQB
Dated: October 16, 2008
Received: October 17, 2008

Dear Mr. Tice:

This letter corrects our substantially equivalent letter of December 5, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081073

Device Name: HDR Vision

Indications For Use:

The HDR Vision is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general RIF, angiography and pediatric examinations.

The HDR Vision is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography and digital subtraction angiography (DSA).

HDR Vision may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.

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Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081073

Indications for use without Letterhead